Trans Tasman Radiation Oncology Group Inc (TROG)
SERIOUS ADVERSE EVENT (SAE) [S1]

Patient Initials | | | |

Patient Trial Registration No. | | | | | | | |

Sex *1=Male 2=Female* |

Weight *(kgs)* | | |

Date of Birth *(dd/Mmm/yyyy)* | | / | | | | / | | | | |

Hospital / Centre

Initial Report ☐
Completed Report ☐
Updated Report ☐

*Complete page 1 & 2 of this form if an SAE is identified on or within 30 days of a patient ceasing protocol treatment. Fax this form to the **TROG Central Operations Office (+61 2 401 43902)** and the **Trial Co-ordinating Centre** within 24 hours of identification of event. If the outcome is 'continuing', re-fax the form when the event is resolved or if death occurs. Refer to the protocol for trial-specific SAE procedures.*

TROG Trial No. | | | | | **Trial Name**

SAE Title *(use CTC term/s to describe)*

Date of Event Onset *(dd/Mmm/yyyy)* | | / | | | | / | | | | |

Category of Event *(tick all that apply)*

- ☐ Results in Death
- ☐ Is Life-Threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Results in Persistent or Significant Disability/Incapacity
- ☐ Requires In-Patient Hospitalisation or Prolongation of Existing Hospitalisation

Cause of Event *(tick all that apply)*

- ☐ Protocol Drug / Chemotherapy Related
- ☐ Radiation Therapy Related
- ☐ Device Related
- ☐ Surgery Related
- ☐ Progressive Disease
- ☐ Concurrent Medication, *specify* ----------
- ☐ Concurrent Disorder, *specify* ----------
- ☐ Other, *specify* ----------

☐ **Is this SAE an 'Expected' Adverse Event** *1= Yes 2=No* → *a known possible radiation reaction, a known possible surgical complication or is identified in nature or severity in the drug product information*

Trial Protocol Drug(s) *(use 'NA' if there are no drugs in protocol treatment regimen)*	**Dose / Day**	**Route**	**First Dose** day 1 of cycle *(dd/Mmm/yy)*	**Last Dose** *(dd/Mmm/yy)*	**Trial Treatment Modifications due to Event (SAE)**	**Trial Treatment Relationship to Event (SAE)**

Action Required
1= none
2= dose/usage reduced
3= ttmt delayed
4= ttmt delayed & dose/usage reduced
5= withdrawn from ttmt

Attribution Codes
1= unrelated
2= unlikely
3= possibly
4= probably
5= definitely

Trial Protocol Radiotherapy *(use 'NA' if there is no RT in protocol treatment regimen)*	**Dose / Fraction**	**Total Dose** *(Gy)*	**First Fraction** *(dd/Mmm/yy)*	**Last Fraction** *(dd/Mmm/yy)*

Trial Protocol Device *(use 'NA' if there is no device in protocol treatment regimen)*	**Device Name**	**First Use** *(dd/Mmm/yy)*	**Last Use** *(dd/Mmm/yy)*

Description of Event: → *Include adverse event (CTC) grade/s, relevant test results, temporal relation to trial treatment and treatment for event. Attach additional pages and/or copies of medical records if necessary.*

Complete Page 2 of SAE Form [S1]

Trans Tasman Radiation Oncology Group Inc (TROG)

SERIOUS ADVERSE EVENT (SAE)

[S1]

Patient Trial Registration No.

TROG Trial No. **Trial Name**

Attach Extra Pages / Copies of Reports if Required to Complete the 'Concomitant Medications', 'Medical History Description' and/or 'Medical Tests/Procedures Performed' Sections of this SAE Report

Concomitant Medications *(include any pharmaceutical products additional to trial protocol drugs)*

Medications (at the time of reaction, use trade names)	**Reason for Use**	**Daily Dosage**	**First Dose** *(dd/Mmm/yy)*	**Last Dose** *(dd/Mmm/yy)*	**Suspect** *(Yes/No)*

Other Relevant Medical History

Medical History Description	**Start Date** *(dd/Mmm/yy)*	**End Date** *(dd/Mmm/yy)*	**Suspect** *(Yes/No)*

Medical Tests/Procedures Performed

Medical Test Description	**Date** *(dd/Mmm/yy)*	**Outcome**

Outcome of Event

- ☐ Recovered without treatment/intervention
- ☐ Recovered with treatment/intervention
- ☐ Patient died

For 'Recovered' or 'Patient Died' enter "Date of Death/Event Resolution" below

- ☐ Event continuing and controlled with treatment
- ☐ Event continuing and not controlled with treatment
- ☐ Event continuing without treatment

For 'Event Continuing' complete "Update: Outcome of Event" section below and re-fax form when patient has recovered or deceased

Date of Death/Event Resolution / /

Investigator Name **Investigator Signature** / / **Date of Report** *(dd/Mmm/yy)*

UPDATE: Outcome of Event

- ☐ Recovered without treatment/intervention
- ☐ Recovered with treatment/intervention
- ☐ Patient died

Date of Death/Event Resolution / /

Investigator Name **Investigator Signature** / / **Date of Updated Report** *(dd/Mmm/yy)*